UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FERRING PHARMACEUTICALS INC., FERRING B.V., and FERRING INTERNATIONAL CENTER S.A., Plaintiffs, v. SERENITY PHARMACEUTICALS, LLC, and REPRISE BIOPHARACEUTICS, LLC, Defendants.	Case No. 1:17-cv-09922 (CM)(SA) ECF Case
SERENITY PHARMACEUTICALS, LLC, and REPRISE BIOPHARACEUTICS, LLC Counterclaim-Plaintiffs, v. FERRING PHARMACEUTICALS INC., FERRING B.V., and FERRING INTERNATIONAL CENTER S.A., Counterclaim-Defendants.	Case No. 1:17-cv-09922 (CM)(SA) ECF Case

MEMORANDUM IN SUPPORT OF SERENITY PHARMACEUTICALS, LLC AND REPRISE BIOPHARMACEUTICS, LLC'S MOTION *IN LIMINE* TO PRECLUDE FERRING FROM OFFERING EVIDENCE OR ARGUMENT RELATED TO DR. FEIN'S RESPONSE TO THE NOTICE OF OPPOSITION IN THE EPO PROCEEDING

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Pursuant to the Court's Order regarding pretrial schedules (D.I. 556) Counterclaimants Serenity Pharmaceuticals, LLC and Reprise Biopharmaceutics, LLC ("Serenity and Reprise" or "Counterclaimants") submit the following motion *in limine* to preclude Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc. ("Ferring") from offering evidence or argument related to Dr. Fein's Response to the Notice of Opposition in the EPO proceeding.

I. BACKGROUND

Ferring initiated an opposition proceeding before the European Patent Office ("EPO"), after Dr. Fein was awarded a European patent (EP-821) for some of his other inventive work—work directed to a specific "metered dose spray device" used for delivery of a specific intranasal dosage form. (DX-37, at 1.) In arguing for revocation of that patent, Ferring argued to the EPO that the claims of Dr. Fein's European "metered dose spray device" patent were invalid in view of numerous prior art references, including the '203 patent at issue here. (*Id*. at 17.) Specifically, Ferring argued that the prior art, including Dr. Fein's '203 patent—in European parlance—"enabled," meaning negated the novelty or inventive step, of Dr. Fein's intranasal dosage form European patent claim that Ferring was opposing. (*Id*.) Ferring now takes "enabled" out of its European context in alleging that Dr. Fein has admitted that the '203 patent claims are not enabled under the U.S. patent laws. But this is simply a matter of a particular word, "enabled," having two entirely different meanings under the U.S. and European patent laws.

In other words, the question in the EPO proceedings was not whether—as here—the asserted claims of the '203 and '321 patents were enabled by the common specification of those patents, as is required under the U.S. patent laws. Instead, the question at issue before the EPO was whether the specific claim of Dr. Fein's European Patent lacked an inventive step (*i.e.* was obvious) in light of the disclosure of Dr. Fein's earlier '203 patent in view of certain other references. (DX-37, at 17.)

The sole European patent claim of EP-821 bears no resemblance to the "method of treatment" claims in the patents-in-suit. The claim at issue in the EPO proceeding reads:

> A composition of matter comprising an intranasal desmopressin dose in the form of a plume ejected over a time interval from the nozzle of a metered dose spray device, the plume comprising a volume of moving droplets together defining a conical volume having a central axis and an apex at the nozzle of the spray device, wherein the droplet density (number of droplets per unit volume) within the conical volume increases in a direction normal to the axis, the droplets together comprising: (a) between 1 μg and 5.0 μg desmopressin; or (b) about 0.75 μg desmopressin, the plume serving to increase contact of the droplets with intranasal luminal mucosal surfaces, wherein said droplets further comprise:
> (a) an oil-in-water emulsion; and
> (b) a cyclopentadecanolide permeation enhancer,
> for use in a method of inducing an antidiuretic effect in a patient, the method comprising intranasally administering the composition to induce antidiuresis for less than about six hours.

(*Id.* at 2.) For example, the asserted claims of the patents-in-suit have nothing to do with "an intranasal desmopressin dose in the form of a plume ejected over a time interval from the nozzle of a metered dose spray device." Likewise, the asserted claims of the patents-in-suit do not call for a "plume" that comprises "a volume of moving droplets together defining a conical volume having a central axis and an apex at the nozzle of the spray device." The asserted claims of the patents-in-suit also say nothing about the use of a "metered dose spray device" to include in the plume "droplets together comprising" desmopressin in specified doses measured in micrograms. The asserted claims of the patents-in-suit do not in any way require "an oil-in-water emulsion." Nor do they call for "a cyclopentadecanolide permeation enhancer"—or any permeation enhancer.

In sum, the "method of treatment" claims in the patents-in-suit are not implicated in any way by the EPO proceeding. Yet, Ferring's Proposed Findings of Fact and Conclusions of Law and direct witness statement of Leo Polz indicate that Ferring intends to put on evidence and argument that the asserted claims—which are irrelevant to the sole issued claim of EP-821—are not enabled based on "Dr. Fein's admissions in front of the EPO." (D.I. 637, Ex. 2).

Counterclaimants, therefore, submit this motion *in limine* to preclude Ferring from introducing any evidence or arguments related to Dr. Fein's August 7, 2018 Opposition Response in the EPO opposition proceedings.

II. LEGAL STANDARD

On a motion *in limine*, a Court may, *inter alia*, preclude evidence on the basis that it is irrelevant, pursuant to FRE 402. *See Island Intellectual Prop. LLC v. Deutsche Bank AG,* 2012 WL 526722, at *3 (S.D.N.Y. Feb. 14, 2012) ("Irrelevant evidence is inadmissible."). Under FRE 403, the court "may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." District courts wield broad discretion in making decisions under this probative-prejudice balancing test. *See Fiacco v. City of Rensselaer*, 783 F.2d 319, 327-28 (2d Cir. 1986); *see also United States v. Abu-Jihaad*, 630 F.3d 102, 131 (2d Cir. 2010) ("We review a district court's evidentiary rulings deferentially, mindful of its superior position to assess relevancy and to weigh the probative value of evidence against its potential for unfair prejudice.").

III. FERRING SHOULD BE PRECLUDED FROM OFFERING EVIDENCE OR ARGUMENTS RELATED TO COUNTERCLAIMANTS' OPPOSITION RESPONSE IN THE EPO PROCEEDING

As discussed above, the opposition proceedings related to EP-821 were not directed to the patents-in-suit. Indeed, Ferring filed that opposition to challenge the grant of a European patent on Dr. Fein's inventive metered dose nasal spray device that incorporates features directed to a plume shape spray of active ingredient droplets and specific permeation enhancers. (DX-37.) Ferring seeks to take the words "not enabled," as used in that EPO submission, and argue—inconsistent with the express provisions of U.S. enablement law—that the method-of-treatment claims of the U.S. '203 patent (which bear no resemblance to the metered dose spray nasal device claimed in the

European patent) were somehow not enabled by the U.S. specification of the '203 patent under 35 U.S.C. §112. (D.I. 637, Ex. 2) Ferring is intentionally confusing the issue, and seeks to present such evidence and arguments notwithstanding an express finding by the U.S. Patent Examiner that the '203 patent claims were, in fact, enabled.

Ferring relies on a document, which, read in context, shows unequivocally that the European Patent Agent was simply arguing (correctly) that the metered dose intranasal spray device did not lack an inventive step in view of the '203 patent. Dr. Fein never admitted that the ***'203 patent*** is not enabled. His European attorney stated, *inter alia*, in response to Ferring's Opposition, that:

> With respect to intranasal dosage form and suitable "low dosage", D8's only teaching is found in col. 16, lines 46-67 and Table in col. 17. Specifically, D8 suggests using an intranasal low dose consisting of 0.1 mcg to 20 mcg daily (see table n col. 17), which can be an effective treatment for clinical indications such as treatment of central diabetes insipidus, prevention primary nocturnal enuresis, and prevention of nocturia (Col. 17, lines 16-19). It is noteworthy that the teaching of D8 with respect to the Table in Col. 17 is not enabled, i.e. there is no examples demonstrating that any of the suggested dose ranges are effective to establish a steady plasma/serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per mL plasma/serum to about 10.0 picogram desmopressin per mL plasma/serum in a patient, let alone provide therapeutic efficacy for the conditions indicated above (e.g., inducing an antidiuretic effect for less than about 6 hours, and which lower the risk of hyponatremia).

(DX-38, at 44.) Thus, Dr. Fein's attorney's response is directed to the specific question of whether his European intranasal dosage form/metered dose spray device is "enabled," under European parlance, by the '203 specification. For example, the Opposition Response states that the '203 patent "is silent about the specific plume geometry and the presence of an oil-in-water emulsion, as well as the specific permeation enhancer CPE, as required in present claim 1. This specific combination of features is not disclosed in [the '203 patent]." (DX-38 at 45.) The Opposition Response further states that "[e]ven if the skilled person would have relied on the teaching of [the '203 patent] as a starting point for establishing a low dose of desmopressin, this information is not

enough to arrive at the [claimed metered dose spray nasal device]." Nothing in the Opposition Response relates to whether the claims of the '203 patent are enabled, as required by U.S. patent law, by the specification of the '203 patent. The "method of treatment" claims in the patents-in-suit are not implicated in any way.

Further, neither Dr. Fein nor the European Patent agent ever said—or intended to say—that the claims of the '203 patent were not enabled under 35 U.S.C. § 112. Dr. Fein's European patent attorney was correct in arguing that the '203 patent specification did not "enable" a claim directed to that kind of sophisticated spray device, as that term is used in the European patent law. But the fact that the '203 patent specification does not "enable" that kind of device is irrelevant to the question at hand in the instant trial: whether Ferring can overcome its high burden of proving by clear and convincing evidence that the U.S. Examiner was wrong in concluding the "method of treatment" claims of the patents-in-suit were enabled by the common specification under the U.S. patent law.

Therefore, the statements made by Dr. Fein's European attorney in response to Ferring's challenge to Dr. Fein's European patent are not relevant to an enablement determination with respect to the patents-in-suit. Because such evidence is irrelevant to any other pending issue, its probative value—if any—is substantially outweighed by confusion of issues, unfair prejudice to Counterclaimants, and waste of time.

IV. CONCLUSION

For these reasons, Serenity and Reprise respectfully request that the Court grant its motion *in limine* to preclude Ferring from offering evidence or argument related to Counterclaimants' Response to the Notice of Opposition in the EPO proceeding.

Dated: February 19, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 19, 2020, the foregoing document was filed electronically through the Court's Electronic Case Filing System. Service of this document is being made upon all counsel of record in this case by the Notice of Electronic Filing issued through the Court's Electronic Case Filing System on this date.

By: *s/ Paul J. Skiermont*